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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/500,033

10/26/2004

Ole Jacob Elle

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER

OROPEZA, FRANCES P

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

07/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/500,033	Applicant(s) ELLE ET AL.	
	Examiner FRANCES P. OROPEZA	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/29/09 (RCE and Request for Reconsider).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/16/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RCE and Response

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/29/09 has been entered.

2. The Applicant's arguments filed 4/29/09 are convincing, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

Claim Rejections - 35 USC § 103

3. Claims 1, 4, 5, 7 and 23-25 are rejected under 35 U.S.C. 103(a) as unpatentable over "Stadler" (U.S. Patent No. 6,115,630 to Stadler et al.) (who incorporates by reference U.S. Patent No. 5,480,412 to Mouchawar et al., who incorporates by reference U.S. Patent No. 5,628,777 to Moberg et al.) in view of "Natarajan" (U.S. Patent No. 6,501,983 to Natarajan et al.) .

Stadler discloses a method and apparatus for properly orienting monitored cardiac information relating to ischemia (abstract; column 1, lines 27-33). An accelerometer is implanted at the apex of the heart. The measured endocardial acceleration signal, which is analyzed in real time, or is recorded in memory for later analysis, correlates well with periods of coronary occlusion, recognized to be periods of ischemia (abstract; column 5, lines 4-10;

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column 12, lines 31-47; column 13, lines 37-49; column 17, lines 25-28; column 28, line 62 - column 29, line 8).

As related to instant claim 7, data collected that relates to detection ischemia is stored in memory for later uplink telemetry transmission (Figure 2 – 120) and for analysis by the physician (column 12, lines 31-33; column 13, lines 8-36).

Stadler incorporates by reference U.S. Patent No. 5,480,412 to Mouchawar et al. (column 28, line 63 – column 29, line 8).

Mouchawar et al. disclose a system and method for deriving hemodynamic signals from a cardiac wall motion sensor, and integrating the signals over time to derive velocity/ speed and acceleration (abstract). The motion sensor is mounted at the distal end of an implantable lead (column. 4, lines 15-26).

As related to instant claim 7, a telemetry system (Figure 3 – 314) enables communication between the implanted device and the external programmer (column 9, lines 16-21).

Mouchawar et al. incorporate by reference U.S. Patent No. 5,628,777 to Moberg et al. (column 2, lines 48-57; column 6, lines 4-6).

Moberg et al. disclose implantable leads that comprising accelerometer-based cardiac wall motion sensors (abstract). The electrode may be a patch electrode, an epicaridal electrode attached to the outer surface of the heart, (Figures 3-6 - 60, 160, 260, 360; column 6, lines 49-54) comprising a motion sensor (Figure 3-6 - 68, 168, 268, 368; column 7, line 30 – column 9, line 48). The patch electrode is sutured in the cardiac wall of the right and/ or left ventricular in the region selected to be monitored, or at the selected position corresponding to the area that is supplied by the selected vessel (column 8, lines 65-67; column 21, lines 18-22).

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As related to instant claims 4 and 24, the lead may also be an endocardial lead comprising a piezoelectric wall motion sensor (Figure 8 – 568; Figures 13-15 - 214; column 14, lines 10-16) and a helically-shaped tip electrode (Figure 8 - 118), the helical shape of the electrode making the electrode removable from its position without requiring surgical intervention.

As related to instant claim 5, the accelerometer-based cardiac wall motion sensors are sensitive along three perpendicular axis (column 3, lines 33-43).

As related to instant claim 7, a telemetry network (256, 258) enables communication between the implanted device and the external device (Figure 18; column 19, lines 3-10).

As discussed in the previous eleven paragraphs of this action, Stadler discloses the claimed invention except for determining a frequency distribution.

Natarajan teaches ischemia monitoring using time-frequency distribution of mechanical parameters such as accelerometer signals for the purpose of measuring movement of the heart as an indication of ischemia. The signal is processed in real time or is recorded in memory for later processing. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used determination of a frequency distribution of the acceleration signals in the Stadler system in order to use a proven means of data analysis that can discern the relative differences in the heart motion and relate it to potential fatal cardiac ischemia, so the patient and the caregivers can receive adequate warning to deal with the situation

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(abstract; column 3, lines 19-47; column 6, line 58 – column 7, line 9; column 10, lines 18-23; column 11, lines 14-19, 49-53; column 11, line 66 – column 12, line 8).

4. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over “Stadler” (U.S. Patent No. 6,115,630 to Stadler et al.) (who incorporates by reference U.S. Patent No. 5,480,412 to Mouchawar et al., who incorporates by reference U.S. Patent No. 5,628,777 to Moberg et al.) and “Natarajan” (U.S. Patent No. 6,501,983 to Natarajan et al.) in view of “Matsumoto” (U.S. Patent No. 6,328,698 to Matsumoto).

As discussed in paragraph 3 of this action, modified Stadler discloses the claimed invention except for the method being performed post operatively in connection with a bypass operation where the area of the heart monitored by the motion sensor is associated with a “revascularised” coronary artery.

Matsumoto teaches a diagnostic system for diagnosing cardiac disease using a three axial accelerometer for the purpose of detecting displacement of the chest wall and teaches monitoring the patient after a bypass procedure where cardiac coronary vascular flow is improved. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the three axial accelerometer for the purpose of monitoring a patient after a bypass procedure where cardiac coronary vascular flow is improved in the modified Stadler et al. system in order to provide a proven means to evaluate the effectiveness of a procedure involving a bypass, and in order to follow the patient's cardiac performance closely during the post-operative period (abstract; column 2, lines 45-50; column 3, lines 45-48, 63-64; column 9, lines 52-64).

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5. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over “Stadler” (U.S. Patent No. 6,115,630 to Stadler et al.) (who incorporates by reference U.S. Patent No. 5,480,412 to Mouchawar et al., who incorporates by reference U.S. Patent No. 5,628,777 to Moberg et al.) and “Natarajan” (U.S. Patent No. 6,501,983 to Natarajan et al.) in view of “Dickinson” (U.S. Patent No. 6,275,724 to Dickinson et al.).

As discussed in paragraph 3 of this action, modified Stadler discloses the claimed invention except for the motion sensor comprising a gyroscope.

Dickinson teaches cardiac monitoring using a three-axis solid state gyroscope or a three-axis accelerometer for the purpose of monitoring the position and location of the catheter. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a three-axis solid state gyroscope in the modified Stadler system in order to provide a known alternative sensor to the accelerometer presently used in the system so the system user has the option to choose the most appropriate motion sensor for the application, and in order that the invention disclosed by Stadler identify additional applications in cardiac medicine (column 1, lines 4-14; column 5, lines 51-54; column 6, lines 2-4; column 9, lines 52-61).

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over “Stadler” (U.S. Patent No. 6,115,630 to Stadler et al.) (who incorporates by reference U.S. Patent No. 5,480,412 to Mouchawar et al., who incorporates by reference U.S. Patent No. 5,628,777 to Moberg et al.) and “Natarajan” (U.S. Patent No. 6,501,983 to Natarajan et al.) in view of “Hess” (U.S. Patent No. 6,328,698 to Hess).

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Stadler teaches an accelerometer implanted at the apex of the heart. The measured endocardial acceleration signal correlate well with periods of coronary occlusion recognized to be period of ischemia (column 28, line 62 - column 29, line 8).

As discussed in the preceding paragraph and in paragraph 3 of this action, modified Stadler discloses the claimed invention except for the motion sensor being incorporated in a temporary pacemaker electrode.

Hess teaches interim pacing using a temporary pacemaker electrode for the purpose of providing stimulus to the heart during medical procedure such as replacement of a cardiac pacemaker. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a temporary lead including a motion sensor in the modified Stadler system in order to effectively monitor the patient after a procedure and to be able to rapidly respond to any cardiac pacing or ischemia issues that might arises (column 1, lines 37-44).

Statutory Basis

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. Fran's schedule typically is Monday and Tuesday 9AM-7PM EST. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's Supervisor, Carl. H. Layno can be

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reached on (571) 272-4949. Carl's schedule typically is Monday, Wednesday, Friday 9AM – 5 PM EST; Tuesday, Thursday 9AM–3PM and 9PM–11PM EST.

The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Frances P. Oropeza/
Patent Examiner, Art Unit 3766
July 15, 2009

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766